THE UNITED STATES PATENT AND TRADEMARK OFFICE P97,1036 ATTY DOCKET NO .: Aark et al. 625,363 **GROUP ART UNIT:** 1801 SERIAL NO

FILED:

February 18, 1998

EXAMINER:

Unknown

NOV 2 4 1998

INVENTION:

"CALORICALLY DENSE NUTRITIONAL COMPOSITION"

SERVICE CENTER

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

Submitted herewith is an Supplemental Information Disclosure Statement for consideration in the above application. This Supplemental Information Disclosure Statement is submitted:

аррпса	non. This Supplemental Information Disclosure Statement is submitted.	
[X]	Within three months (1) of filing date of a national application; (2) of date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; or (3) before the mailing date of a first Office Action of the merits, whichever occurs last. (No fee is required.)	
[]	After the mailing date of a first Office Action but before (1) mailing of a final action under 37 C.F.R. §1.113; of (2) mailing of a notice of allowance under §1.311, whichever occurs first.	
	[] Payment of the fee set forth in 37 C.F.R. §1.17(p) accompanies this submission; or	
	[] The certification specified in 37 C.F.R. §1.97(e) is made below. (No fee is required.)	
[]	After the mailing of (1) a final action under 37 C.F.R. §1.113; or (2) notice of allowance under 37 C.F.R. §1.31 whichever occurs first, but before payment of the issue fee. The certification specified in 37 C.F.R. §1.97(e) is made below. The Commissioner hereby is petitioned to consider the Information Disclosure Statement accompanying this submission. Payment for the Petition fee set forth in 37 C.F.R. §1.17(i)(1) accompanies this submission.	
[]	The undersigned counsel for applicant(s) hereby certifies each item of information identified in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.	
[]	The undersigned counsel for applicant(s) hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the statement.	
[]	A check in the amount of \$ to cover any required fee is enclosed.	
[X]	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 08-2290. A duplicate copy of this sheet is enclosed for this purpose.	
	Very respectfully,	

HILL & SIMPSON A Professional Corporation

When phoning re this application, please call (312) 876-0200.

(Reg. No. 30,142)

Hill & Simpson, P.C. Sears Tower, 85th Floor Chicago, Illinois 60606 Telephone: (312) 876-0200

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C 20231 November 15, 1998.

ROBERT M. BARRETT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:

David A. Mark et al.

ATTY DOCKET NO.:

P97,1036

SERIAL NO:

09/025,363

GROUP ART UNIT:

1801

FILED:

February 18, 1998

EXAMINER:

Unknown

INVENTION:

"CALORICALLY DENSE NUTRITIONAL COMPOSITION"

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT TRANSMITTAL LETTER

Assistant Commissioner for Patents Washington, D.C. 20231

SIR:

plemental Information Disclosure Statement for consideration in the above-identified

applicat	ion. This Supplemental Information Disclosure	e Statement is submitted:	
[X]	Within three months (1) of filing date of a nathernation for thin 37 C.F.R. §1.491 in an international the merits, whichever occurs last. (No fee is	tional application; (2) of date of entry of the national stage as set application; or (3) before the mailing date of a first Office Action on required.)	
[]	After the mailing date of a first Office Action (2) mailing of a notice of allowance under §1	but before (1) mailing of a final action under 37 C.F.R. §1.113; or .311, whichever occurs first.	
	[] Payment of the fee set forth in 37 C	C.F.R. §1.17(p) accompanies this submission; or	
	[] The certification specified in 37 C.I	F.R. §1.97(e) is made below. (No fee is required.)	
[]	After the mailing of (1) a final action under 37 C.F.R. §1.113; or (2) notice of allowance under 37 C.F.R. §1.311 whichever occurs first, but before payment of the issue fee. The certification specified in 37 C.F.R. §1.97(e) is made below. The Commissioner hereby is petitioned to consider the Information Disclosure Statement accompanying this submission. Payment for the Petition fee set forth in 37 C.F.R. §1.17(i)(1) accompanies this submission.		
[]	The undersigned counsel for applicant(s) hereby certifies each item of information identified in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.		
[]	The undersigned counsel for applicant(s) hereby certifies that no item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, or to the knowledge of the undersigned, after making reasonable inquiry, was known to any individual designated in 37 C.F.R. §1.56(c) more than three months prior to the filing of the statement.		
[].	A check in the amount of \$ to cover any required fee is enclosed.		
[X]	The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Account No. 08-2290. A duplicate copy of this sheet is enclosed for this purpose.		
		Very respectfully,	
		HILL & SIMPSON A Professional Corporation	
When phoning re this application, please call (312) 876-0200.		Hill & Simpson, P.C. Sears Tower, 85th Floor Chicago, Illinois 60606 Telephone: (312) 876-0200	

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C 20231 November 15, 1998. 20

ROBERT M. BARRETT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

APPLICANT:

David A. Mark et al.

ATTY DOCKET NO.:

P97,1036

SERIAL NO:

09/025,363

GROUP ART UNIT:

1801

FILED:

February 18, 1998

EXAMINER:

Unknown

INVENTION:

"CALORICALLY DENSE NUTRITIONAL COMPOSITION"

Assistant Commissioner for Patents

Washington, D.C. 20231

SIR:

In accordance with the provisions of 37 C.F.R. § 1.56, Applicants request that citation and examination of the references identified on the attached PTO-1449 form, copies of which are enclosed herewith in accordance with 37 C.F.R. 1.98, be made during the course of examination of the above-mentioned application for United States Patent.

OTHER DOCUMENTS

Alexander et al., "Beneficial Effects of Aggressive Protein Feeding in Severely Burned Children", *Ann. Surg.*, Vol. 192, No. 4, 1980, pp. 505-517.

Anderson et al., "Intestinal Protein Loss During Enteral Alimentation in Critically Ill Patients", *J Parenter Enteral Nutr.*, Vol. 14 (Suppl), No. 1, 1990, pg. 24, Abstract.

August et al., "Determination of Zinc and Copper Absorption at Three Dietary Zn-Cu Ratios by Using Stable Isotope Methods in Young Adult and Elderly Subjects", *Am J Clin Nutr*, Vol. 50, 1989, pp. 1457-1463.

Austin, "Water: Guidelines for Nutritional Support", *Nutritional Support Services*, Vol. 6, No. 9, 1986, pp. 27-29.

Belcher et al., "Determinants of Urinary Nitrogen Excretion in Burned Patients", *Burns*, Vol. 14, No. 4, 1988, pp. 303-307.

Bjerve et al., "Alpha-Linolenic Acid Deficiency in Patients on Long-Term Gastric-Tube Feeding: Estimation of Linolenic Acid and Long-Chain Unsaturated n-3 Fatty Acid Requirement in Man", *Am J Clin Nutr*, Vol. 5, 1987, pp. 66-77.

Bogden et al., "Zinc and Immunocompetence in Elderly People: Effects of Zinc Supplementation for 3 Months", *Am J Clin Nutr*, Vol. 48, 1988, pp. 655-663.

Bogden et al., "Zinc and Immunocompetence in the Elderly: Baseline Data on Zinc Nutriture and Immunity in Unsupplemented Subjects", *Am J Clin Nutr*, Vol. 46, 1987, pp. 101-109.

Breslow, "Nutritional Status and Dietary Intake of Patients With Pressure Ulcers: Review of Research Literature 1943 to 1989", *Decubitus*, Vol. 4, No. 1, 1991, pp. 16-21.

Brinson, "The Effect of Peptide-Based Diets on the Intestinal Microcirculation in a Rat Model", *Nutr Clin Prac*, Vol. 5, 1990, pp. 238-240.

Brinson et al., "Diarrhea Associated With Severe Hypoalbuminemia: A Comparison of a Peptide-Based Chemically Defined Diet and Standard Enteral Alimentation", *Critical Care Medicine*, Vol. 16, No. 2, 1988, pp. 130-136.

Brinson et al., "Intestinal Absorption of Peptide Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats: A Paired Analysis", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 657-660.

Bynoe et al., "Nutrition Support in Trauma Patients", *Nutr Clin Prac*, Vol. 4, 1988, pp. 137-144.

Cerra et al., "Enteral Nutrition in Hypermetabolic Surgical Patients", *Critical Care Medicine*, Vol. 17, No. 7, 1989, pp. 619-622.

Cerra et al., "The Effect of Stress Level, Amino Acid Formula, and Nitrogen Dose on Nitrogen Retention in Traumatic and Septic Stress", *Ann. Surg.*, Vol. 205, No. 3, 1987, pp. 282-287.

Cerra et al., "What's New in Nutrition Support in Critical Care", *Perspective in Clinical Nutrition*, Kinney, Borum (Eds.), Urban & Schwarzenberg: Baltimore-Munich, 1989, pp. 323-338.

Chandra, "Trace Element Regulation of Immunity and Infection", *Journal of the American College of Nutrition*, Vol. 4, No. 1, 1985, pp. 5-16.

D'Atellis et al., "Branched-Chain Amino Acids", *Nutrition in Critical Care*, In Zaloga (ed.), St. Louis, MO: Mosby, 1994, pp. 81-106.

Dominioni et al., "Enteral Feeding in Burn Hypermetabolism: Nutritional and Metabolic Effects of Different Levels of Calorie and Protein Intake", *Journal of Parenteral and Enteral Nutrition*, Vol. 9, No. 3, 1985, pp. 269-279.

Dominioni et al., "Prevention of Severe Postburn Hypermetabolism and Catabolism by Immediate Intragastric Feeding", *J. Burn Care Rehab.*, Vol. 5, No. 2, 1984, pp. 106-112.

Ehrlich et al., "Effects of Cortisone and Vitamin A on Wound Healing", *Annals of Surgery*, Vol. 167, No. 3, 1968, pp. 324-328.

Ehrlich et al., "Effects of Vitamin A and Glucocorticoids upon Inflammation and Collagen Synthesis", *Ann. Surg.*, Vol. 177, No. 2, 1973, pp. 222-227.

Ehrlich et al., "Effects of Beta-Carotene, Vitamin A, and Glucocorticoids on Collagen Synthesis in Wounds", *Proc. Soc. Exp Biol Med.*, Vol. 137, No. 1, 1971, pp. 936-938.

Fabiani et al., "Oral Hyperalimentation in the Nutritional Management of Burned Patients", SAMJ, Vol. 67, 1985, pp. 768-770.

Freeman et al., "Effects of Magnesium Infusions on Magnesium and Nitrogen Balance During Parenteral Nutrition", *The Canadian Journal of Surgery*, Vol. 25, No. 5, 1982, pp. 570-574.

Goodson et al., "Wound Healing", *Nutrition and Metabolism in Patient Care*, In: Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, 635-642.

Gottschlich et al., "Enteral Nutrition in Patients with Burns or Trauma", *Clinical Nutrition Enteral and Tube Feeding 2nd Edition*, In: Rombeau et al. (Eds.), Philadelphia, PA: WB Saunders, 1990, pp. 306-324.

Gottschlich et al., "Vitamin Supplementation in the Patient with Burns", J. Burn Care Rehab., Vol. 11, No. 3, 1990, pp. 275-279.

Granger et al., "Intestinal Absorption of Elemental and Standard Enteral Formulas in Hypoproteinemic (Volume Expanded) Rats", *Journal of Parenteral and Enteral Nutrition*, Vol. 12, No. 3, 1988, pp. 278-281.

Hadley et al., "Nutrition and Wound Healing", *Top Clin. Nutr.*, Vol. 5, No. 4, 1990, pp. 72-81.

Hallbook et al, "Serum-Zinc and Healing of Venous Leg Ulcers", *Lancet*, 1972, pp. 780-782.

Hunt, "Control of Wound Healing With Cortisone and Vitamin A", *The Ultrastructure* of Collagen, In: Longacre JJ (ed.), Springfield, IL: Charles C. Thomas, 1976, pp. 497-508.

Hunt et al., "Effect of Vitamin A on Reversing the Inhibitory Effect of Cortisone on Healing of Open Wounds in Animals and Man", *Annals of Surgery*, Vol. 170, No. 4, 1969, pp. 633-641.

Hunt et al., "Selenium Depletion in Burn Patients", Journal of Parenteral and Enteral Nutrition, Vol. 8, No. 6, 1984, pp. 695-699.

Ireton-Jones et al., "Nutrition for Adult Burn Patients: A Review", *Nutr. Clin Prac.*, Vol. 6, No. 1, 1991, pp. 3-7.

Jahoor et al., "Dynamics of the Protein Metabolic Response to Burn Injury", *Metabolism*, Vol. 37, No. 4, 1988, pp. 330-337.

Johnson et al., "Metabolism of Medium-Chain Triglyceride Lipid Emulsion", *Nutrition International*, Vol. 2, No. 3, 1986, pp. 150-158.

Kissileff et al., "Physiology of the Control of Food Intake", *Ann. Rev. Nutr.*, Vol. 2, 1982, pp. 371-418.

Kubo et al., "Fluid and Electrolyte Problems of Tube-Fed Patients", *American Journal of Nursing*, Vol. 76, No. 6, 1976, pp. 912-916.

Levenson, "Micronutrients (Vitamins, Trace Minerals)", In ASPEN Program Manuel of Proceedings of The 16th Clinical Congress, 1992, pp. 189-198.

Long et al., "Metabolic Response to Injury and Illness: Estimation of Energy and Protein Needs from Indirect Calorimetry and Nitrogen Balance", *Journal of Parenteral and Enteral Nutrition*, Vol. 3, No. 6, 1979, pp. 452-456.

Mandt et al., "Nutritional Requirements", *Nutrition Support Handbook*, In: Teasley-Strausberg (ed.), Cincinnati, OH: Harvey Whitney Books Co., 1992, pp. 19-36.

McClave et al., "Immunonutrition and Enteral Hyperalimentation of Critically Ill Patients", *Digestive Diseases and Sciences*, Vol. 37, No. 8, 1992, pp. 1153-1161.

Meredith et al., "Visceral Protein Levels in Trauma Patients Are Greater with Peptide Diet Than with Intact Protein Diet", *The Journal of Trauma*, Vol. 30, No. 7, 1990, pp. 825-829.

Ortiz et al., "A Comparative Post-Operative Study - An Enteral Solution Based on Free Amino Acids, *Gastroenterologic Clinique et Biologique*, Vol. 9, No. 2, 1985, pp. 182-183.

Pearson et al., "An Estimation of the Potassium Requirements For Equilibrium in Burned Patients", Surgery Gynecology & Obstetrics, Vol. 112, No. 3, 1961, pp. 263-273.

Pories et al., "Acceleration of Wound Healing in Man With Zinc Sulphate Given By Mouth", *Lancet*, 1967, pp121-124.

Prasad et al., "Serum Thymulin in Human Zinc Deficiency", J. Clin. Invest., Vol. 82, 1988, pp. 1202-1210.

Ringsdorf et al., "Vitamin C and Human Wound Healing", *Oral Surgery*, Vol. 53, No. 3, 1982, pp. 231-236.

Ross et al., "Wound Healing and Collagen Formation - II. Fine Structure in Experimental Scurvy", *The Journal of Cell Biology*, Vol. 12, 1962, pp. 533-551.

Ross et al., "Wound Healing and Collagen Formation - V. Quantitative Electron Microscope Radioautographic Observations of Proline-H³ Utilization by Fibroblasts", *The Journal of Cell Biology*, Vol. 27, 1965, pp. 83-106.

Ross et al., "Vitamin A as a Hormone: Recent Advances in Understanding the Actions of Retinol, Retinoic Acid, and Beta Carotene", *Journal of The American Dietetic Association*, Vol. 93, No. 11, 1993, pp. 1285-1290.

Sandstead et al., "Zinc and Wound Healing: Effects of Zinc Deficiency and Zinc Supplementation", *The American Journal of Clinical Nutrition*, Vol. 23, No. 5, 1970, pp. 514-519.

Silk, "Nutritional Support in Hospital Practice", Oxford, Blackwell Scientific Publications, 1983, pp. 79-82.

Spiller et al., "Malabsorption", *Nutrition and Metabolism in Patient Care*, Kinney et al. (Eds.), Philadelphia, PA: WB Saunders, 1988, pp. 281-304.

Stotts et al., "Nutrition: A Critical Component of Wound Healing", *AACN Clin Issues*, Vol. 1, No. 3, 1990, pp. 585-594.

Szebeni et al., "Vitamin A Levels in the Serum of Burned Patients", *Burns*, Vol. 7, No. 5, 1981, pp. 313-318.

Waxman et al., "Protein Loss Across Burn Wounds", *The Journal of Trauma*, Vol. 27, No. 2, 1987, pp. 136-140.

Ziegler et al., "Efficiency of Enteral Nitrogen Support in Surgical Patients: Small Peptides v Non-Degraded Proteins", *Gut*, Vol. 31, 1990, pp. 1277-1283.

Applicants look forward to early and favorable consideration of this matter.

Respectfully submitted,

(Reg. No. 30,142)

Robert M. Barrett HILL & SIMPSON A Professional Corporation 85th Floor Sears Tower Chicago, Illinois 60606 (312) 876-0200

ATTORNEY FOR APPLICANTS

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited in the United States Postal Service, First Class Mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on November 13, 1998.